What is claimed is :

1. A process for preparing a humanized antibody comprising the steps of:

(a) selecting a specificity determining residue (SDR) of the complementarity determining region (CDR) of murine monoclonal antibody heavy chain and light chain variable regions; and

(b) grafting said SDR to at least one of the corresponding amino acid sequences into human antibody variable regions.

2. The process of claim 1, wherein step (a) is conducted by replacing each the amino acid residues of CDR with alanine to produce transformants, selecting a transformant that has lower affinity to the human antigen (K_D) than the original murine antibody and determining the replaced amino acid residue of said transformant as an SDR.

3. The process of claim 2, wherein the CDR is selected from the group consisting of HCDR1(aa 31-35), HCDR2(aa 50-65) and HCDR3(aa 95-102) of the heavy chain (SEQ ID NO: 2); and LCDR1(aa 24-34), LCDR2(aa 50-56) and LCDR3(aa 89-97) of the light chain (SEQ ID NO: 4) of the murine monoclonal antibody variable regions of hepatitis B virus pre-S1 antigen, selecting a transformant that has an affininty to antigen which is more than 3 times lower than the original murine antibody when replaced with alanine, determining the replaced amino acid residue of said transformant as an SDR, and grafting said SDR to the corresponding amino acid sequence in human antibody heavy chain and light chain

4. The process of claim 3, which is characterized in that the at least one of Trp33, Met34, and Asn35 of HCDR1; Arg50, Tyr52, and Pro52a of HCDR2; and Glu95, Tyr96, and Glu98 of HCDR3 of the murine monoclonal antibody KR127 heavy chain, is grafted to the corresponding amino acid sequences in human antibody heavy chain.

5. The process of claim 4, which is characterized in that the at least one of the following grafting steps is carried out:

(a) the amino acid residue at position 32 in HCDR1 of human

antibody with alanine;

(b) the amino acid residue at position 97 in HCDR3 of human antibody with arginine or alanine;

(c) the amino acid residue at position 98 in HCDR3 of human antibody with valine; and

(d) the amino acid residue at position 102 in HCDR3 of human antibody with arginine or alanine.

6. The process of claim 5, which is characterized in that the at least one of Trp33 and Asn35 of HCDR1; Arg50 and Tyr52 of HCDR2; and Arg95 and Tyr96 of HCDR3 of the murine monoclonal antibody KR127 heavy chain, is grafted into the human antibody heavy chain DP7-JH4.

7. The process of claim 6, which is characterized in that the amino acid residues of the Ala71 and Lys73 in Framework region 3 of the murine monoclonal antibody KR127 heavy chain variable region, of further grafted into the human antibody heavy chain DP7-JH4.

8. The process of claim 3, which is characterized in that the at least one of the Leu27b, Tyr27d, Ser27e, Asn28, Lys30, Tyr32 and Asn34 of LCDR1; Leu50 and Asp55 of LCDR2; and Val89, Gln90, Gly91, Thr92, His93, Phe94, Pro95, and Gln96 of LCDR3 of the murine monoclonal antibody KR127 light chain, is grafted into the human antibody light chain.

9. The process of claim 8, which is characterized in that the Tyr27d, Asn28, Asn34 of LCDR1; Leu50 and Asp55 of LCDR2; and Val89, Gly91, Thr92, His93, Phe94, Pro95, and Gln96 of LCDR3 of the murine monoclonal antibody KR127 light chain, is grafted into the human antibody light chain DPH12-JK4.

10. The process of claim 8, which is characterized in that the Leu36 and Arg46 in Framework region 2 of the murine monoclonal antibody KR127 light chain variable region, are further grafted into the human antibody light chain DPH12-JK4.

11. A humanized antibody prepared by the process of any one of

claims 1 to 10, which has an affinity to antigen of higher than 8.2×10^{-9} M and suppresses HAMA (human anti-mouse antibody) response to a greater extent than an antibody prepared according to CDR-grafting method.

12. The humanized antibody of claim 11, which has the amino acid sequence of SEQ ID NO: 2 for the heavy chain variable region of HBV pre-S1 antigen.

13. The humanized antibody of claim 11, which has the amino acid sequence of SEQ ID NO: 4 for the light chain variable region of HBV pre-S1 antigen.

14. The humanized antibody of any one of claims 11 to 13, which is produced by CHO/HuKR127 (Accession No.: KCTC 10199BP).

15. A DNA encoding the humanized antibody heavy chain containing the amino acid sequence of SEQ ID NO: 2 for the heavy chain variable region of HBV pre-S1 antigen.

16. The DNA of claim 15, wherein the variable region has the nucleotide sequence of SEQ ID NO: 1.

17. A DNA encoding the humanized antibody light chain containing the amino acid sequence of SEQ ID NO: 4 for the light chain variable region of HBV pre-S1 antigen.

18. The DNA of claim 17, wherein the variable region has the nucleotide sequence of SEQ ID NO: 3.

19. An expression vector pHuKR127HC comprising the DNA of claim 16 for expressing the humanized antibody heavy chain for HBV pre-S1 antigen.

20. An expression vector pHuKR127KC comprising the DNA of claim 18 for expressing the humanized antibody light chain for HBV pre-S1 antigen.

21. An expression vector pdCMV-dhfrC-HuKR127 comprising both the DNAs of claim 16 and 18 for expressing the humanized antibody light and heavy chains for HBV pre-S1 antigen.

22. An *E. coli* DH5α/pdCMV-dhfrC-HuKR127 (Accession No.: KCTC 10198BP) transformed with the expression vector of claim 21.

23. CHO cell line CHO/HuKR127 (Accession No.: KCTC 10199BP) producing the humanized antibody of claim 11.

24. A composition for preventing or treating HBV infection comprising the humanized antibody of any one of claims 11 to 13.